

## REMARKS/ARGUMENTS

The rejections presented in the Office action dated September 12, 2005 have been considered. Claims 1-48 are pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

The abstract was objected to because of the length. The abstract has been amended to comply with the length requirement.

Claim 27 was objected to due to an informality. Claim 27 has been amended to correct the informality noted by the Examiner. This amendment does not narrow the scope of the claim.

Claims 7, 11, 16, and 22-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. These claims have been amended to obviate the rejections. None of the amendments are made for purposes of patentability relative to the art of record, nor do any of the amendments have a narrowing effect on the scope of the claims.

Claims 1-3, 5-7, 9, 10, 12, 13, 16, 25, 30, 32, 35, 37-39, and 44 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,867,163 to *Schaldach* (hereinafter "Schaldach").

To anticipate a claim, the asserted reference must teach every element of the claim. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. All claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102.

Applicant respectfully disagrees with the Examiner's characterization of Schaldach and the contention that Schaldach anticipates these claims. Applicant respectfully asserts that features recited in independent claims 1, 32, and 44 are not disclosed or suggested in Schaldach.

Applicant's invention, as set forth, for example, in claims 1, 32, and 44 is directed to methods, devices and systems involving implantable production, storage, and

communication of an audio signal and implantable production, storage, and communication of a cardiac electrical signal.

In contrast to Applicant's invention, Schaldach does not teach or suggest producing, storing and/or communicating an audio signal. Applicant asserts that an "audio signal" is capable of generating "audio" (an audible sound) during playback. There is no teaching in Schaldach that an audio signal is produced, stored and/or communicated to a patient-external device.

Schaldach teaches a cardiac pacemaker capable of controlling pacing based on "physiological measured or input variables." (col. 7, lines 27-30 and col. 8, line 6) Schaldach states that control of pacing may use "measured values pickups" that measure such variables as blood temperature, impedance, blood oxygen saturation, or pH. Schaldach mentions "pressure or sound pickups for measured values that have a relationship to mechanical contractions." (col. 7 lines 53-61). At col. 20, lines 67-68 Schaldach describes that the pressure or sound pickups measure stroke volume which is used in controlling pacing, including pacing rate.

Applicant respectfully asserts that Schaldach's use of a pressure sensor or microphone such as to measure stroke volume does not correspond to producing an audio signal as recited in claims 1, 32, and 44. In contrast to Applicant's claims, Schaldach only describes measuring stroke volume using a pressure sensor or microphone. The measured value of stroke volume described by Schaldach would not produce audio and thus can not reasonably be construed as an audio signal as the term is generally understood by those skilled in the art. Furthermore, Schaldach does not describe storing an audio signal.

Additionally, Schaldach clearly does not describe communicating an audio signal to a patient-external device as recited in Applicant's claims 1, 32, and 44. Applicant refers to Figures 6b-6e through which Schaldach describes the patient-external graphical interface used for modifying pacing parameters. In each of these examples, Schaldach graphically depicts information from the "characteristic fields" described by Schaldach as being "stored in memories . . . such as are used in the above described pacemaker concept." Graphical depiction of the characteristic fields in Figures 6b-6e shows the variation of load (L) or cardiac output (HZV) with respect to heart rate (HR) and stroke

volume (SV). These graphs depict how HR, and/or SV change the cardiac output or load. There is no teaching or suggestion by Schaldach that an audio signal is produced, stored or communicated. Schaldach only teaches that a microphone may be used to derive measured values such as stroke volume, but does not teach that an audio signal is produced from the microphone, or that any such audio signal is stored and/or communicated to a patient-external device.

Schaldach does not teach or suggest all of the claim limitations of Applicant's independent claims 1, 32, and 44, therefore, these claims are not anticipated by Schaldach. Dependent claims 2, 3, 5-7, 9, 10, 12, 16, 35, and 37-39, which are dependent from independent claims 1, 32, or 44, respectively, were also rejected under 35 U.S.C. §102(b) as being unpatentable over Schaldach. Applicant does not acquiesce with the particular rejections to any of the dependent claims 2, 3, 5-7, 9, 10, 12, 16, 35, and 37-39 but believes these rejections are moot in view of the comments provided above. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 2, 3, 5-7, 9, 10, 12, 16, 35, and 37-39 are also patentable over Schaldach. Applicant reserves the right to further address the rejections of these dependent claims if the rejections are maintained.

Furthermore, regarding the rejection of claims 2 and 35, the Applicant disagrees that the characteristic field comprises the acceleration signal.

Applicant asserts that the accelerometer signal is used to detect patient activity. An indication of patient activity, not the acceleration signal itself, is used in connection with the "characteristic field." See, for example, Schaldach col. 20, lines 12-17: "A digital activity sensor 522 furthermore recognizes, by the appearance of accelerations and decelerations beyond a predetermined threshold value, whether the patient at the time is generally at rest or in motion and switches the characteristic field located in block 520 over accordingly." Applicant contends that there is no teaching that a characteristic field comprises the acceleration signal.

Regarding the rejection of claim 30 and 38, Applicant respectfully asserts that the passage indicated by the Examiner does not teach that signals are time correlated. Signals are not time correlated just by virtue of the fact that they are concurrently

displayed. One skilled in the art would not interpret the term “time correlated” to mean that two signals are displayed on a monitor at the same time. Col. 20, line 46 of Schaldach merely says that two characteristic fields may be superimposed, but does not teach that these two characteristic fields are time correlated as it would be understood by a person skilled in the art.

Claims 17, 19-21, 41, 45, and 46 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Schaldach.

With regard to the rejection under 35 U.S.C. § 102(b) Applicant respectively disagrees that these claims are anticipated by Schaldach. Independent claim 17 includes the limitations that an audio signal (a signal that is capable of producing audio) is produced, stored, and communicated. Applicant reasserts arguments set forth above in connection with claims 1, 32, and 44 regarding Schaldach’s failure to teach or suggest producing, storing, and communicating an audio signal.

In addition, claim 17 recites a patient-external device including a user interface “configured for providing a visual output representative of the cardiac electrical signal and an audio output representative of the audio signal.” The device described by Schaldach clearly does not produce an audio output representative of the audio signal.

In order to make Schaldach’s graphical output reach claim 17, the Examiner takes the position that “any manifestation of an audio signal is an audio output.” Applicant disagrees with this analysis. The word “audio” is defined as “sound” in The New Oxford American Dictionary and in the American Heritage Dictionary. Applicant asserts that the usual meaning of the word “audio” is sound, and thus an audio output is a sound output. Further, Applicant’s position is bolstered by the language of claim 17 itself which recites a “user interface configured for providing a **visual output** representative of the cardiac electrical signal and an **audio output** representative of the audio signal.” Applicant contends that a visual output is an output that can be seen and an audio output is an output that can be heard. Applicant’s position is further supported by the language of claim 18, which is dependent on claim 17: Claim 18 recites that “the user interface is configured for providing a visual output representative of the audio signal,” thus by claim differentiation, the audio output of the audio signal recited in claim 17 is different from

the visual output of the audio signal recited in claim 18. Schaldach does not teach or suggest a user interface that provides an audio output as recited in Applicant's claim 17.

For at least the reasons set forth above, Schaldach does not teach all of the claim limitations of independent claim 17. Therefore, independent claim 17 and claims 19-21 which depend therefrom are not anticipated by Schaldach.

Claims 17, 19-21, 41, 45, and 46, in the alternative, stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Schaldach.

Applicant respectfully disagrees and asserts that the Examiner has failed to make a case of *prima facie* obviousness of the rejected claims in view of Schaldach. Three criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference, or combination of references, must teach or suggest all the claim limitations. MPEP § 2142.

Regarding the third criterion listed above, Applicant respectfully contends that Schaldach fails to teach or suggest all of the claim limitations of the rejected claims. For example, with respect to claim 17, Applicant reasserts the arguments presented above setting forth Schaldach's failure to teach or suggest the limitations of claim 17. The Examiner states that "it is well known in the art to provide audio signals representative of audio events of the heart, for example, by stethoscope or speaker."

It would appear that the Examiner is impermissibly taking official notice that limitations that are not taught or suggested by the asserted reference, Schaldach, constitute facts outside of the record which are capable of instant and unquestionable demonstration as being well known or obvious to one skilled in the art. Applicant hereby traverses the Official Notice and, in accordance with MPEP § 2144.03, requests the Examiner to cite a reference in support of the Official Notice that it is well known to implantably produce and store an audio signal, transfer the audio signal to a patient-external device, and to provide an audio output of the audio signal along with all the other limitations of claim 17. In particular, the Examiner is requested to provide evidence that discloses all of the steps of claim 17, and also that provides motivation for modifying any reference or for combining references.

The Examiner is referred to MPEP § 2144.03 regarding Official Notice. Allegations concerning specific knowledge of the prior art...should be supported and the applicant should be given the opportunity to challenge the correctness of such assertions and allegations. The facts so noticed serve to “fill the gaps” which might exist in the evidentiary showing and should not comprise the principle evidence upon which a rejection is based. MPEP § 2144.03, citing *In re Ahlert* 424 F.2d 1088, 1091, 165 USPQ 418, 420-421 (CCPA 1970).

Furthermore, Applicant contends that combining the use of a stethoscope or speaker with the teachings of Schaldach has no reasonable expectation of success. For example, a stethoscope, although capable of amplifying cardiac sounds and producing an acoustic signal, is not implantable and does not produce an audio signal that can be stored and transferred. Furthermore, a speaker only produces sound when driven with an audio signal. As set forth in arguments above, Schaldach does not teach that an audio signal is produced, stored or transferred, therefore, no sound would be generated by the speaker suggested by the Examiner.

Because the asserted references fail to teach or suggest several of the above-identified limitations, and because there is no evidence to support a sufficient basis to support a reasonable expectation of success or the requisite suggestion or motivation to combine or modify the references in the manner suggested by the Examiner, Applicant respectfully asserts that the Examiner has failed to establish *prima facie* obviousness of Applicants’ subject matter recited in independent claim 17 and the dependent claims therefrom.

Dependent claims 19-21, 41, 45, and 46 which depend from independent Claims 17, 32, or 44, were also rejected under 35 U.S.C. §103(a) as being unpatentable over Schaldach. While Applicant does not acquiesce with any particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 17, 32, or 44. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. “If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.” M.P.E.P. §2143.03; citing *In re Fine*, 837 F.2d 1071, 5

USPQ2d 1596 (Fed. Cir. 1988). Therefore, dependent claims 19-21, 41, 45, and 46 are also allowable over the Schaldach.

Rejections of various dependent claims are summarized as follows: Claims 4 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schaldach in view of U.S. Patent No. 6,477,406 to *Turcott* (hereinafter “Turcott”). Claims 8, 11, and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schaldach in view of U.S. Patent No. 5,935,081 to *Kadhiresan* (hereinafter “Kadhiresan”). Claims 14, 18, 22-24, 31, 33, 34, 43, and 47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schaldach in view of U.S. Patent No. 5,321,618 to *Gessman* (hereinafter “Gessman”). Claims 15, 26-29, 42, and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schaldach in view of U.S. Patent Publication No. 2002/0026223 to *Riff* (hereinafter “Riff”).

Each of these dependent claims depends from independent claim 1, 17, 32, or 44. For the reasons set forth above, independent claims 1, 17, 32, and 44 are not anticipated or obvious in view of Schaldach. Although Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent 1, 17, 32, and 44. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, dependent claims 4, 8, 11, 14, 15, 18, 22-24, 26-29, 31, 33, 32, 36, 40, 42, 43, 47, and 48 are also in condition for allowance.

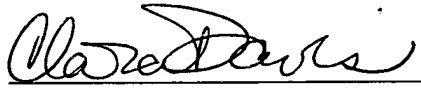
Applicant does not acquiesce to Examiner’s characterization of the asserted art or Applicant’s claimed subject matter, nor of the Examiner’s application of the asserted art or combinations thereof to Applicant’s claimed subject matter. Moreover, Applicant does not acquiesce to the Examiner’s statements or conclusions concerning what would have been obvious to one of ordinary skill in the art, obvious design choices, common knowledge at the time of Applicant’s invention, officially noticed facts, and the like. Applicant reserves the right to address in detail the Examiner’s characterizations, conclusions, and rejections in future prosecution.

If the Examiner believes it necessary or helpful, the undersigned attorney of record invites the Examiner to contact her at 952.854.2700 to discuss any issues related to this case.

Respectfully submitted,

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